UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,283	04/24/2001	Robert W. Schrier	CRNC.86595	5323

46169 7590 01/26/2006

SHOOK, HARDY & BACON L.L.P.
Intellectual Property Department
2555 GRAND BOULEVARD
KANSAS CITY, MO 64108-2613

EXAMINER	
PASS, NATALIE	
ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/842,283	SCHRIER ET AL.	
	Examiner	Art Unit	
	Natalie A. Pass	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/24/01, 4/14/03, 11/7/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 24 April 2001, the Preliminary Amendment filed 14 April 2003 and the Response to Restriction Requirement filed 7 November 2005. Claims 1 and 14-21 have been cancelled. Claims 2-13 have been elected, and are pending.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 2-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,317,719. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite elements that are substantially the same and that would have been obvious to one of ordinary skill in the art.

(A) Claim 2 of the present application is substantially word-for-word identical to portions of claim 1 of the '719 patent (column 33, lines 40-57). In particular, the Schrier '719 patent teaches a method of creating an electronic prescription (Schrier; column 33, lines 41-42), comprising the steps of:

interactively receiving an input from a user selecting a medication (Schrier; column 33, lines 43-44);

displaying to the user alternative elements for creating an electronic prescription for the currently selected medication, including the routes associated with the medication, the dose amounts in which the medication is available in a formulary for a chosen route, the dose forms in which the medication is available in the formulary for a chosen route, and the frequencies of

administration associated with the medications and a chosen route (Schrier; column 33, lines 45-53); and

receiving from the user an input accepting an order including the user selected medication, frequency of administration, route of administration, dose amount and dose form (Schrier; column 33, lines 54-57).

The difference appears to be the replacement of the term "electronic prescription" of column 33, lines 41 and 46 with "electronic medication order" in the preamble and with "electronic order" in line 4 of presently claimed 1, the replacement of the term "accepting an order" of column 33, line 54 with "accepting an electronic order" in presently claimed 1, the insertion of the term "the alternative elements" in line 5 of presently claimed 1, and the deletion of the terms "in a formulary" and "in the formulary" from column 33, lines 49 and 50-51 respectively.

However, the skilled artisan, when considering that the preamble of the patented invention defines the patented invention to be a "method for creating an electronic prescription," (Schrier; column 33, lines 41-42) would have readily recognized that this is, in essence, a "method for creating an electronic medication order."

Similar analysis holds for claims 3-6 of the present application and claims 2-5 of the Schrier '719 patent.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 2-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The statutory status of the instant claims under Section 101 will be analyzed with guidance from MPEP Section 2106.

(A) Claims 2, 8, 10 and 12 recite in their preambles a "method for creating an electronic medication order," and claim 7 recites in the preamble a "system for creating an electronic prescription for a patient." The limitations in the body of the claims, however, recite receiving and displaying steps and components but no creating steps or components. For a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, claims 2, 7, 8, 10 and 12 recite useful and concrete (i.e. capable of receiving and displaying and repeatable) but not tangible result for there is no provision in the body of the claim to permit the functionality claimed in the preamble to be realized

(B) Dependent claims 3-6, 9, 11, and 13 recite "receiving" and "sending" and "determining" steps that also fail to define any structural or functional interrelationships to permit the functionality claimed in the preamble to be realized, and therefore provide no tangible result as well, and are rejected for the same reasons given above for claims 2, 7, 8, 10, and 12, incorporated herein.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 2, 8, 10 and 12 recite in their preambles a "method for creating an electronic medication order," and claim 7 recites in the preamble a "system for creating an electronic prescription for a patient." The limitations in the body of the claims, however, recite "receiving" and "displaying" steps and components but no creating steps or components. It is unclear where, within the body of these claims, a creation of electronic medication orders or electronic prescriptions occurs. Dependent claims 3-6, 9, 11, and 13 recite "receiving" and "sending" and "determining" steps but also fail to recite creating steps or components.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 2, 4, 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Villa-Real, U.S. Patent Number 4,293,845.

(A) As per claims 2, 4, Villa-Real teaches a method for creating an electronic medication order, comprising:

interactively receiving an input from a user selecting a medication (Villa-Real; column 3, lines 20-21);

displaying to the user alternative elements for creating an electronic order for the currently selected medication, the alternative elements including the routes associated with the medication (Villa-Real; column 7, lines 33-40), the dose amounts in which the medication is available for a chosen route (Villa-Real; column 5, lines 30-36), the dose forms in which the medication is available for a chosen route (Villa-Real; column 6, lines 10-19), and the frequencies of administration associated with the medication and a chosen route (Villa-Real; column 3, lines 47-51);

receiving from the user an input accepting an electronic order including the user selected medication (Villa-Real; column 6, lines 1-2), frequency of administration (Villa-Real; column 6, lines 3-4), route of administration (Villa-Real; column 7, lines 33-40), dose amount (Villa-Real; column 5, lines 30-36, column 6, lines 7-8) and dose form (Villa-Real; column 6, lines 9-19); and

determining which ordering alternatives to display to a user by accessing "stored previous information" (reads on "an electronic database of associations") (Villa-Real; column 6, lines 45-51) comprising an association of routes with medications, an association of routes with medications and routes with dose forms, and an association of routes and medications with frequencies of administration (Villa-Real; column 3, lines 47-51, column 5, lines 25-36, column 6, lines 1-35, 45-51, column 7, lines 34-40, column 7, line 57 to column 8, line 2).

(B) As per claim 6, Villa-Real teaches a method as analyzed and discussed in claims 2 and 4 above wherein the medication order is represented by an electronic order record comprising:

a name of the medication (Villa-Real; column 6, lines 1-2);

a unique medication "code number" (reads on "identifier") (Villa-Real; column 3, lines 30-36);

a medication dose size (Villa-Real; column 5, lines 30-36);

a medication route of administration (Villa-Real; column 7, lines 33-40);

a medication form (Villa-Real; column 6, lines 10-19);

and a medication daily frequency (Villa-Real; column 6, lines 3-4).

(C) Claim 7 differs from method claim 2, in that it is a system for creating an electronic prescription for a patient rather than a method for creating an electronic medication order.

System claim 7 repeats the subject matter of claim 2, respectively, as a set of elements rather than a series of steps. As the underlying processes of claim 2 have been shown to be fully disclosed by the teachings of Villa-Real in the above rejection of claim 2, it is readily apparent that the system disclosed by Villa-Real includes the apparatus to perform these functions. As such, these limitations are rejected for the same reasons given above for method claim 2, and incorporated herein.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 3, 5, 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villa-Real, U.S. Patent Number 4,293,845, as applied to claim 2 above, and further in view of Brimm et al., U.S. Patent Number 5,072,383.

(A) As per claim 3, Villa-Real teaches a method as analyzed and discussed in claim 2 above, further comprising:

interactively receiving an input from the user selecting when the medication should be administered (Villa-Real; column 3, lines 20-33).

Villa-Real fails to explicitly disclose

whether a generic substitute is acceptable for the medication; and

sending the order electronically to a pharmacy.

However, the above features are well-known in the art, as evidenced by Brimm.

In particular, Brimm teaches

whether a generic substitute is acceptable for the medication (Brimm; column 10, lines 23-26); and

sending the order electronically to a pharmacy (Brimm; column 6, lines 44-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Villa-Real to include inputting whether a generic substitute is acceptable for the medication; and sending the order electronically to a pharmacy, as taught by Brimm, with the motivations of enabling automatic updates to electronic patient records and of automatically recording the completion of tasks and interventions as performed to complete the documentation requirement for proper patient care (Brimm; column 3, 47-54).

(B) As per claim 5, Villa-Real teaches a method as analyzed and discussed in claims 2 and 4 above.

Villa-Real fails to explicitly disclose

wherein the database of associations contains a record for each available combination.

However, the above features are well-known in the art, as evidenced by Brimm.

In particular, Brimm teaches

wherein the database of associations contains a record for each available combination (Brimm; Figure 2, Item 64, Figure 3, Item 38, Figure 5, Figure 9, column 9, lines 12-37).

The motivations for combining the respective teachings of Villa-Real and Brimm are as given in the rejection of claim 2 above, and incorporated herein.

(C) Claim 8 differs from claim 2 in that it recites displaying a plurality of routes and a plurality of dose forms to the user.

As per claim 8, Villa-Real teaches a method for creating an electronic medication order, comprising;

receiving an input from a user selecting a medication (Villa-Real; column 3, lines 20-21);

displaying to the user a plurality of routes in which the selected medication is available (Villa-Real; column 7, lines 33-40); and

displaying to the user a plurality of dose forms for the selected medication and route (Villa-Real; column 6, lines 1-19) and receiving an input from a user selecting a dose form (Villa-Real; column 6, lines 1-19).

Although Villa-Real teaches receiving an input from a user selecting various features, such as medication, duration, dosage, quantity and form (Villa-Real; column 6, lines 1-19), and although Villa-Real teaches another embodiment in which a plurality of routes are displayed (Villa-Real; column 7, lines 33-40), Villa Real fails to explicitly disclose receiving an input from a user selecting a route.

However, the above features are well-known in the art, as evidenced by Brimm.

In particular, Brimm teaches

receiving an input from a user selecting a route (Brimm; column 10, lines 55-60).

The motivations for combining the respective teachings of Villa-Real and Brimm are as given in the rejection of claim 2 above, and incorporated herein.

(D) As per claim 9, Villa-Real and Brimm teach a method as analyzed and discussed in claim 8 above

further comprising receiving an input from the user accepting the electronic medication order including the user selected medication, route and dose form(Villa-Real; column 5, lines 30-36, column 6, lines 1-19, column 7, lines 33-40).

(E) Claim 10 differs from claim 2 in that it recites displaying a plurality of routes and a plurality of dose amounts to the user.

As per claim 10, Villa-Real teaches a method for creating an electronic medication order, comprising;

receiving an input from a user selecting a medication (Villa-Real; column 3, lines 20-21);

displaying to the user a plurality of routes in which the selected medication is available (Villa-Real; column 7, lines 33-40); and

displaying to the user a plurality of dose amounts for the selected medication and route (Villa-Real; column 6, lines 1-19) and receiving an input from a user selecting a dose form (Villa-Real; column 6, lines 1-19).

Although Villa-Real teaches receiving an input from a user selecting various features, such as medication, duration, dosage, quantity and form (Villa-Real; column 6, lines 1-19), and although Villa-Real teaches another embodiment in which a plurality of routes are displayed (Villa-Real; column 7, lines 33-40), Villa Real fails to explicitly disclose receiving an input from a user selecting a route.

However, the above features are well-known in the art, as evidenced by Brimm.

In particular, Brimm teaches

receiving an input from a user selecting a route (Brimm; column 10, lines 55-60).

The motivations for combining the respective teachings of Villa-Real and Brimm are as given in the rejection of claim 2 above, and incorporated herein.

(F) As per claim 11, Villa-Real and Brimm teach a method as analyzed and discussed in claim 10 above

further comprising receiving an input from the user accepting the electronic medication order including the user selected medication, route and dose amount (Villa-Real; column 5, lines 30-36, column 6, lines 1-19, column 7, lines 33-40).

(G) Claim 12 differs from claim 2 in that it recites displaying a plurality of routes and a plurality of frequencies to the user.

As per claim 12, Villa-Real teaches a method for creating an electronic medication order, comprising;

receiving an input from a user selecting a medication (Villa-Real; column 3, lines 20-21);

displaying to the user a plurality of routes in which the selected medication is available (Villa-Real; column 7, lines 33-40); and

displaying to the user a plurality of frequencies for the selected medication and route (Villa-Real; column 6, lines 1-19) and receiving an input from a user selecting a frequency (Villa-Real; column 6, lines 1-19).

Although Villa-Real teaches receiving an input from a user selecting various features, such as medication, duration, dosage, quantity and form (Villa-Real; column 6, lines 1-19), and although Villa-Real teaches another embodiment in which a plurality of routes are displayed (Villa-Real; column 7, lines 33-40), Villa Real fails to explicitly disclose receiving an input from a user selecting a route.

However, the above features are well-known in the art, as evidenced by Brimm.

In particular, Brimm teaches

receiving an input from a user selecting a route (Brimm; column 10, lines 55-60).

The motivations for combining the respective teachings of Villa-Real and Brimm are as given in the rejection of claim 2 above, and incorporated herein.

(H) As per claim 13, Villa-Real and Brimm teach a method as analyzed and discussed in claim 10 above

further comprising receiving an input from the user accepting the electronic medication order including the user selected medication, route and frequency (Villa-Real; column 5, lines 30-36, column 6, lines 1-19, column 7, lines 33-40).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied references, Rose et al., U.S. Patent Number 4, 695, 954, Maestre, U.S. Patent Number 5, 347, 453, Goldfischer, et al., U.S. Patent Number 4, 839, 806, Howson, U.S. Patent Number 5, 088, 981, and Gombrich et al., U.S. Patent Number 4, 857, 716 teach the environment of creating electronic medication orders.

14. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington D.C. 20231

or faxed to: **(571) 273-8300.**

For informal or draft communications, please label "PROPOSED" or "DRAFT" on the front page of the communication and do NOT sign the communication. After Final communications should be labeled "Box AF."

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (571) 272-3600.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Natalie A. Pass

January 20, 2006

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER